UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/519,035 | 12/22/2004 | Sandra De Meyer | TIP0014 US | 7001 |

27777 7590 09/20/2005

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| EXAMINER | |
|---|---|
| WANG, LOUISE Z | |
| ART UNIT | PAPER NUMBER |
| 1648 | |

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,035 | DE MEYER ET AL. | |
| | Examiner | Art Unit | |
| | Louise Wang | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's Preliminary Amendment, filed 22 December 2004, is acknowledged.

*Claims 1-20 are pending.*

It is noted that claims 3 and 4 are missing a space between the words "strain" and "comprising". Appropriate correction is required.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 and 2, drawn to the special technical feature of a computer system comprising at least one database correlating the presence of at least one mutation in a human immunodeficiency virus (HIV) protease and a change in susceptibility of at least one strain of HIV to a protease inhibitor, comprising at least one record corresponding to a correlation between at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E in said protease, and treatment with at least a protease inhibitor.

Group II, claims 3, 4, 9, and 10, drawn to the special technical feature of a method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant HIV strain or for evaluating a change in viral drug susceptibility, comprising:

(i) collecting a sample from an HIV-infected patient;

(ii) determining whether the sample comprises a nucleic acid encoding HIV protease having at least one mutation selected from 41 S, 41T, 41I, 41K, 41G and 70E;

(iii) correlating the presence of said at least one mutation of step (ii) to a change in effectiveness of said protease inhibitor or in viral drug susceptibility.

Group III, claims 5 and 6, drawn to the special technical feature of a method for identifying a drug effective against mutant HIV protease, comprising:

(i) providing a nucleic acid comprising mutant HIV protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;

(ii) recombining said nucleic acid comprising mutant HIV protease of step (i) into a pro-viral nucleic acid deleted for said sequence to generate a recombinant HIV virus;

(iii) determining a phenotypic response to said drug for said HIV recombinant virus; and

(iv) identifying a drug effective against mutant HIV based on the phenotypic response of step (iii).

Group IV, claims 7, 8, 13, and 14, drawn to the special technical feature of a method for identifying a drug effective against mutant HIV protease, comprising:

(i) providing a HIV protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;

(ii) determining the activity of said drug on said HIV protease;

(iii) determining the activity of said drug on wild type HIV protease;

(iv) determining the ratio of the activity determined in step (iii) over the activity determined in step (ii);

(v) identifying an effective drug against mutant HIV based on the ratio of step (iv).

Group V, claims 11 and 12, drawn to the special technical feature of a method for evaluating a change in viral drug susceptibility, comprising:

(i) providing an HIV comprising a protease comprising at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E;

(ii) determining a phenotypic response of said virus to said drug; and

(iv) correlating the phenotypic response of step (ii) to a change in viral drug susceptibility.

Group VI, claims 15 and 16, drawn to the special technical feature of a vector for performing phenotypic analysis comprising an HIV sequence having at least one mutation in the HIV protease gene chosen from 41S, 41T, 41I, 41K, 41G and 70E.

Group VII, claims 17 and 18, drawn to the special technical feature an isolated and purified HIV protease sequence having at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E, wherein said at least one mutation in said sequence correlates to a fold change in susceptibility towards a HIV protease inhibitor.

Group VIII, claims 19 and 20, drawn to the special technical feature of an isolated and purified oligonucleotide comprising a HIV protease sequence of 5 to 100 bases for in vitro diagnosis of viral drug resistance, characterized in that said oligonucleotide comprises at least one mutation chosen from 41S, 41T, 41I, 41K, 41G and 70E.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each group requires a special technical feature that is not present in any of the other groups.

Furthermore, the special technical feature in Group I is a computer system comprising at least one database correlating the presence of at least one mutation in a human immunodeficiency virus (HIV) protease and a change in susceptibility of at least one strain of HIV to a protease inhibitor, comprising at least one record corresponding to a correlation between at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E in said protease, and treatment with at least a protease inhibitor. However, it is not an improvement over the prior art of Shafer *et al.* (Jan, 1999).

Shafer teaches the HIV RT and Protease Sequence Database with all published HIV protease sequences linked to data about the source of the sequence sample and

the anti-HIV drug treatment history of the individual from whom the isolate was obtained (see entire document, in particular, Figure 2). The reference specifically teaches using the database for functional and clinical correlates of HIV protease sequence changes. See Medical Relevance.

Since Applicant's inventions are not a contribution over the prior art, they lack a special technical feature, they cannot be said to have unity of invention.

***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Irrespective of which Group is elected, Applicant is required to select one mutation in HIV protease.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Joint Inventorship***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Contact Information***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

L. Wang
Patent Examiner
8 September, 2005

JEFFREY STUCKER
PRIMARY EXAMINER